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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,268	06/22/2001	Pananchukunath Manoj Kumar	RLL-178US	8724

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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	PAPER NUMBER
1615	6

DATE MAILED: 08/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/888,268	KUMAR ET AL.	
	Examiner	Art Unit	
	Micah-Paul Young	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-18 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-18 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1 – 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ayer et al (USPN 3980778) in view Vilkov et al (USPN 5807579). Claims 1 – 9 are drawn to an oral formulation comprising an antihistamine with an average particle size between 0.1 and 15 microns. The antihistamine is loratadine, and the formulation further comprises fillers such as saccharides, and celluloses, binders, such as starch and polyvinylpyrrolidone and lubricants such as magnesium stearate and various waxes. The dosage can be in the form of a tablet, capsule or suspension. Claims 10 – 18 are drawn to a process for making the formulation of claims 1 – 9 where the drug is milled into the specific particle size.

Ayer at al discloses a drug formulation for oral and topical administration comprising fillers, binders and lubricants. One of the active ingredients can be an antihistamine, and the

formulation calls for the active agent to be ball milled to sizes below 5 microns. The formulation comprises lactose, methylcellulose, starch, and magnesium stearate (col. 11, lin. 44 – 53; examples). The formulation differs from the claimed invention in that is does not name the antihistamine of applicant, though it is known in the art.

Vilkov et al discloses a pharmaceutical tablet containing antihistamines such as azatadine and loratadine. The formulation further comprises other excipients, such as lubricants, fillers and plasticizers (col. 4, lin. 1 – 43).

One difference not addressed by the art is the surface are of the particles. It is known in the art that in order to increase the dissolution rate (and bioavailability) of a compound, the surface area must increase, thereby decreasing the particle size. In claims 1, 2, 10 and 12 applicant recites specific surface areas, along with particle sizes. It is the position of the examiner that in view of the knowledge in the art, which discloses the particle size of applicant that the recitation of surface area, one of ordinary skill in the art would be able to determine and obtain the surface area through routine experimentation. Barring a showing of criticality to the specific surface and unexpected results of said surface area, limitation is deemed non-critical and do not distinguish the claimed invention from the prior art.

Therefore one of ordinary skill in the art would have been motivated to incorporate the particles of Vilkov into the formulation and process of Ayer in order to impart antihistamine properties onto the preparations. A skilled artisan would have followed the suggestion of Ayer to include antihistamines into the formulation. It would have been obvious to one of ordinary skill in the art, at the time of the invention to combine the teachings of the art with the expected result of an oral tablet formulation with antihistamine, and improve dissolution properties.

Conclusion

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Weintraub et al (USPN 4013785) teaches an oral formulation comprising antihistamines, binders, fillers and other excipients. Cuca et al (USPN 5494681) teaches an oral dosage form comprising antihistamines, binders, fillers, etc. where the drug particles measure 10 and 400 microns.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005. The examiner can normally be reached on M-F 7:30am-4: 30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-7648 for regular communications and 703-746-7648 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Micah-Paul Young
Examiner
Art Unit 1615

MPY
August 19, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600